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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/304,564 05/04/99 CHOKRI

M USD-93-AG-ID

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HM22/0327

EXAMINER

HOLLERAN, A

ART UNIT

PAPER NUMBER

1642

DATE MAILED:

03/27/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/304,564

Applicant(s)

Chokri et al

Examiner

Anne Holleran

Group Art Unit

1642



☒ Responsive to communication(s) filed on Jan 4, 2001

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 3-5 is/are pending in the applicat

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 3-5 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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**DETAILED ACTION**

1. This Office Action is responsive to the Amendment filed January 4, 2001. Claims 1 and 2 were canceled. Claims 3-5 were added.

Claims 3-5 are examined on the merits.

***Claim Rejections Withdrawn:***

2. The rejection of claims 1 and 2 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendment canceling claims 1 and 2.

3. The rejection of Claims 1 and 2 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 5,959,084 (Ring et al., published Sep. 28, 1999; effective filing date Oct. 29, 1990) is withdrawn in view of the amendment canceling claims 1 and 2.

***Claim Rejections Maintained and New Grounds of Rejection:***

4. Claims 3-5 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention. Evidence that claims 3-5 fail to correspond in scope with that which applicant(s) regard as the invention can be found in Paper No. 7 filed January 4, 2001. In that paper, applicant has stated that Applicant's macrophages are distinguished over the prior art and have the unique properties recited in the claims because of the

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incubation medium used, and this statement indicates that the invention is different from what is defined in the claim(s) because the claimed methods do not recite macrophages that were incubated in any specific medium.

5. The rejection of Claim 1 under 35 U.S.C. 102(b) as being anticipated by Chokri et al (Chokri, M. et al., Res. Immunol, 143: 95-99, 1992) is withdrawn in view of the amendment canceling claim 1 and applied to new claims 3-5.

Claim 3 is drawn to a method for treating cancer comprising administering macrophages and bispecific antibodies. The macrophages have at least one of the following properties: cytotoxic activity that is increased by 20 to 30 percent over standard macrophages in the absence of interferon-gamma; cytotoxic activity that is increased by 20 to 40 percent over standard macrophages in the presence of interferon-gamma; deactivation of cytotoxic activity is at a rate such that 60 hours after activation by interferon-gamma the cytotoxic activity is at least 30 percent of the maximum cytotoxic activity due to interferon-gamma stimulation. Claim 4 is drawn to a method wherein the macrophages are injected at the same time as the bispecific antibodies. Claim 5 is drawn to a method wherein the macrophages are preincubated with the bispecific antibodies before administration.

Chokri et al teach a method of treating tumors by administration of macrophages and bispecific antibodies which recognizes both the FcγRI of macrophages and recognizes human adenocarcinoma antigen (see abstract). The macrophages increase cytotoxic activity compared to standard macrophages by about 20 to 40 percent in the presence of interferon-gamma (see Table

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II, page 98). Chokri et al teach precoating the macrophages with bispecific antibodies (preincubation of macrophages) and simultaneous administration of macrophages and bispecific antibodies (see page 97, 2nd column). Thus, Chokri et al teach methods which are the same as that claimed.

6. The rejection of Claims 1 and 2 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 5,635,600 (Fanger et al., published June 3, 1997; effective filing date Feb. 2, 1988) is withdrawn in view of the amendment canceling claims 1 and 2 and is applied to new claims 3-5.

U.S. Patent 5,635,600 discloses methods of treating cancer by administering bispecific antibodies and macrophages (column 5, lines 17-28 and column 5, line 61- column 6, line 27), where the macrophages may be armed with the bispecific antibodies (reads on simultaneous administration and preincubation of the macrophages). The macrophages may be treated with interferon-gamma. Absent evidence to the contrary, the macrophages of U.S. Patent 5,635,600 will exhibit the same potential characteristics that are listed in claim 3 for activation of macrophages by interferon-gamma. Thus, U.S. Patent 5,635,600 discloses methods which are the same as that claimed.

7. The rejection of Claims 1 and 2 under 35 U.S.C. 102(b) as being anticipated by WO 91/05871 (Medarex, Inc., published 2 May 1991) is withdrawn in view of the amendment canceling claims 1 and 2 and is applied to new claims 3-5.

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WO 91/05871 teaches methods for treating cancer by administering bispecific antibodies and macrophages (page 5, lines 5-21; page 6, line 19 to page 7, line 3), where the macrophages may be armed with the bispecific antibodies (reads on simultaneous administration and preincubation of macrophages). The macrophages may be treated with interferon-gamma. Absent evidence to the contrary, the macrophages of WO 91/05871 will exhibit the same potential characteristics that are listed in claim 3 for activation of macrophages by interferon-gamma. Thus, WO 91/05871 teaches methods which are the same as that claimed.

### *Conclusion*

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892.


Examiner Holleran can normally be reached Monday through Friday, 9:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

ALH

Anne L. Holleran  
Patent Examiner  
March 22, 2001

  
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